UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,512	06/15/2006	Eddy Jean Edgard Freyne	PRD-2170USPCT	7466
27777 7590 02/25/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA			EXAMINER	
			JARRELL, NOBLE E	
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003		4	ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)					
Office Action Commence	10/596,512	FREYNE ET AL.					
Office Action Summary	Examiner	Art Unit					
	Noble Jarrell	1624					
The MAILING DATE of this communication ap Period for Reply	opears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING ID. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period. - Failure to reply within the set or extended period for reply will, by statul Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin I will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).					
Status							
1)⊠ Responsive to communication(s) filed on <u>15</u> .	lune 2006						
	· · · · · · · · · · · · · · · · · · ·						
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)⊠ Claim(s) <u>1-18</u> is/are pending in the application	n.						
,—	4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) is/are allowed.							
7) Claim(s) is/are objected to.							
8) Claim(s) 1-18 are subject to restriction and/or	election requirement						
, , , , , , , , , , , , , , , , , , , ,	olosilon roquiromenti						
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureat * See the attached detailed Office action for a list	nts have been received. Its have been received in Applicationity documents have been received in Applicationity documents have been received in the contract of the contract	on No ed in this National Stage					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate					

Application/Control Number: 10/596,512 Page 2

Art Unit: 1624

DETAILED ACTION

1. Claims 1-18 are pending in the current application. This is a National Stage of PCT/EP04/53501, filed 12/15/2004.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 4, 7, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where $a^1-a^2-a^3-a^4$ is –CH-CH=N-CH-, Z is NH, X^2 is N-Ak, Y is Ak-C(O)N-Ak and X^1 is N.

Group II, claim(s) 1-2, 4,7, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where $a^1-a^2-a^3-a^4$ is –CH-CH=N-CH-, Z is NH, X^2 is NC(O)Ak, Y is Ak- N-Ak and X^1 is N.

Group III, claim(s) 1-2,4-6, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where $a^1-a^2-a^3-a^4$ is -N-CH=CH-CH-, Z is NH, X^2 is NC(O)Ak, Y is Ak- N-Ak and X^1 is N.

Group IV, claim(s) 1-2,4-6, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where a^1 - a^2 - a^3 - a^4 is –N-CH=CH-CH-, Z is NH, X^2 is Het²⁰-Ak where Het²⁰ is pyrrolidine, Y is C(O)N-Ak and X^1 is N.

Group V, claim(s) 1-6, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where $a^1-a^2-a^3-a^4$ is -N-CH=CH-CH-, Z is NH, X^2 is O-Ak, Y is Ak-C(O)N-Ak and X^1 is N.

Group VI, claim(s) 1-2,4-6, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where $a^1-a^2-a^3-a^4$ is -N-CH=CH-CH-, Z is NH, X^2 is N-Ak, Y is Ak-C(O)N-Ak and X^1 is N.

Group VII, claim(s) 1-2, 4, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I where a^1 - a^2 - a^3 - a^4 is –N-CH=N-CH-, Z is NH, X^2 is NC(O)Ak, Y is Ak-N-Ak and X^1 is N.

Group VIII, claim(s) 1-7, 9-12,15-17, drawn to compounds, compositions, and a method of using compounds of formula I not covered by groups I-VII.

Group IX, claims 8-14, 17-18 drawn to compounds, compositions, and a method of using compounds, of formula XXXI.

The inventions listed as Groups I-# do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- (f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.
- (i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:
 - (A) All alternatives have a common property or activity; and
 - (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
 - (B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables Z, X², Y, and X¹ result in compounds that

Application/Control Number: 10/596,512

Art Unit: 1624

have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

```
=> d que sta 19
VAR G1=C/N
VAR G2=O/N/S
REP G3=(G-4) A
REP G4=(2-15) A
NODE ATTRIBUTES:
DEFAULT MLEVEL IS ATOM
DEFAULT ECLEVEL IS LIMITED
GRAPH ATTRIBUTES:
ring(s) are isolated or embedded
NUMBER OF NODES IS 20
STEREC ATTRIBUTES: NONE
=> 19
STRUCTURE TOO LARGE - SEARCH ENDED
A structure in your query is too large. You may delete
attributes or atoms to reduce the size of the structure
and try again.
```

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Page 5

3. Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different core ring structures or patentably distinct compounds. Invention IX is patentably distinct because it requires a separate structural query than inventions I-VIII. Inventions I-VIII are each patentably distinct because each invention represents a different core.

Claim 1 is generic to the following disclosed patentably distinct species: compounds of groups I-IX. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*for searching purposes only*) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a species to be examined even though the requirement <u>may</u> be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected

species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

Application/Control Number: 10/596,512 Page 7

Art Unit: 1624

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Application/Control Number: 10/596,512 Page 8

Art Unit: 1624

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/ Examiner, Art Unit 1624 /James O. Wilson/ Supervisory Patent Examiner Art Unit 1624